

1.5.5 PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

ADCO-CEFTRIAZONE 500 mg (Powder for Injection)

ADCO-CEFTRIAZONE 1 g (Powder for Injection)

ADCO-CEFTRIAZONE 2 g (Parenteral Infusion)

ADCO-CEFTRIAZONE 500 mg: Each vial contains 500 mg sterile ceftriazone as ceftriazone sodium.

ADCO-CEFTRIAZONE 1 g: Each vial contains 1 g sterile ceftriazone as ceftriazone sodium.

ADCO-CEFTRIAZONE 2 g: Each vial contains 2 g sterile ceftriazone as ceftriazone sodium.

Sugar Free

Read all of this leaflet carefully before you are given ADCO-CEFTRIAZONE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What ADCO-CEFTRIAZONE is and what it is used for
2. What you need to know before you are given ADCO-CEFTRIAZONE
3. How to use ADCO-CEFTRIAZONE

4. Possible side effects
5. How to store ADCO-CEFTRIAZONE
6. Contents of the pack and other information

1. What ADCO-CEFTRIAZONE is and what it is used for

ADCO-CEFTRIAZONE is an antibiotic given to adults and children (including new-born babies) that belongs to a group of medicines called cephalosporins. It works by killing bacteria that cause infections.

ADCO-CEFTRIAZONE is used to treat infections of:

- the brain (meningitis);
- the middle ear;
- the abdomen and abdominal wall (peritonitis);
- the urinary tract and kidneys;
- bones and joints;
- the skin or soft tissues;
- the blood;
- the lungs;
- the ear, nose and throat
- the intestines.

It can be given:

- to treat specific sexually transmitted infections (gonorrhoea);
- to prevent infections during surgery.

2. What you need to know before you are given ADCO-CEFTRIAZONE

ADCO-CEFTRIAZONE should not be administered to you:

- if you are hypersensitive (allergic) to ceftriaxone or any of the other ingredients of ADCO-CEFTRIAZONE (listed in section 6);
- if you are hypersensitive (allergic) to cephalosporins or penicillin's.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- if you have recently received or are about to receive products that contain calcium;
- if you have a coagulation (blood clot) disorder;
- if you have recently had diarrhoea after having an antibiotic medicine;
- if you have ever had problems with your gut, in particular colitis (inflammation of the bowel);
- if you have gall stones or kidney stones.

You may experience inflammation of the pancreas, biliary obstruction (blockage of any duct that carries bile from the liver to the gallbladder and small intestine) when you are treated with ADCO-CEFTRIAZONE.

Children

Talk to your doctor or pharmacist or nurse before your child is administered ADCO-CEFTRIAZONE if he/she has recently been given or is to be given a medicine that contains calcium into their vein.

Your doctor will take caution when considering ADCO-CEFTRIAZONE treatment if your child is hyperbilirubinaemic (too much bilirubin in your baby's blood).

Other medicines and ADCO-CEFTRIAZONE

Always tell your health care provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

ADCO-CEFTRIAXONE can affect the results of urine tests for sugar and a blood test known as the Coombs' test. If you are diabetic or need to have your blood glucose level monitored you should not use certain blood glucose monitoring systems which may estimate blood glucose incorrectly while you are receiving ADCO-CEFTRIAXONE. If you use such systems check the instructions for use and tell your doctor, pharmacist or nurse. Alternative testing methods should be used if necessary.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Ceftriaxone crosses the placental barrier and is passed into breast-milk.

Safety in pregnancy and lactation has not been established.

Driving and using machines

ADCO-CEFTRIAXONE may affect your mental and/or your physical abilities to perform or execute tasks or activities requiring your mental alertness, judgment and/or sound coordination and vision.

3. How to use ADCO-CEFTRIAXONE

ADCO-CEFTRIAXONE be given as a drip (intravenous infusion) or as an injection directly into a vein or into a muscle.

You will not be expected to give yourself ADCO-CEFTRIAXONE. It will be given to you by a person who is qualified to do so.

Your doctor will tell you how long your treatment with ADCO-CEFTRIAXONE will last. If you have the impression that the effect of ADCO-CEFTRIAXONE is too strong or too weak, tell your doctor or pharmacist.

The usual dose

Your doctor will decide the correct dose of ADCO-CEFTRIAXONE for you. The dose will depend on the severity and type of infection; whether you are on any other antibiotics; your weight and age and how well your kidneys and liver are working.

If you take more ADCO-CEFTRIAXONE than you should

Since a health care provider will administer ADCO-CEFTRIAXONE, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use ADCO-CEFTRIAXONE

Since a health care provider will administer ADCO-CEFTRIAXONE, it is unlikely that the dose will be missed.

4. Possible side effects

ADCO-CEFTRIAXONE can have side effects.

Not all side effects reported for ADCO-CEFTRIAXONE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ADCO-CEFTRIAXONE, please consult your health care provider for advice.

If any of the following happens, stop using ADCO-CEFTRIAXONE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,

- Anaphylactic shock and anaphylactoid reactions (serious life-threatening allergic reaction which usually occurs within few seconds or minutes of exposure to allergic substances. This involves hives, swelling and sudden drop in the blood pressure and sometimes shock).
- Severe skin reactions: Exanthema (a skin rash accompanying a disease or fever), allergic dermatitis (skin irritation), pruritis (itching), urticaria (hives), oedema (swelling caused due to excess fluid accumulation in the body tissues). Stevens-Johnson syndrome or Lyell's syndrome/ toxic epidermal necrolysis (severe skin reaction with blisters or peeling of the skin and possibly blisters in the mouth).

These are all very serious side effects. If you have them, you may have had a serious reaction to ADCO-CEFTRIAXONE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Nausea;
- Vomiting;
- Headache;
- Dizziness;
- Loose stools/ diarrhoea;
- Stomatitis (inflammation of the mouth and lips);
- Glositis (problem in which the tongue is swollen and inflamed);
- Precipitation of ceftriaxone salts in the gallbladder;
- Increase in liver enzymes;
- Thrombocytopenia, leukopenia, lymphopenia, eosinophilia, granulocytopenia, agranulocytosis (disorders of the blood);
- Haematoma or bleeding
- Hemolytic anaemia (a disorder in which red blood cells are destroyed faster than they

can be made.);

- Oliguria (low urine output);
- Genital mycosis (fungal infection);
- Phlebitic reactions (inflammation of veins causing pain, discomfort and swelling);

These are all serious side effects. You may need urgent medical attention.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of ADCO-CEFTRIAXONE.

5. How to store ADCO-CEFTRIAXONE

Store in a dry cool place, at or below 25 °C, protected from light.

Storage directions for reconstituted product: Store for up to 6 hours at 25 °C or 24 hours at 2 – 8 °C.

Single dose unit. Discard any unused portion of solution.

KEEP OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What ADCO-CEFTRIAXONE contains

The active substance is ceftriaxone;

ADCO-CEFTRIAZONE 500 mg: Each vial contains 500 mg sterile ceftriazone as ceftriazone sodium.

ADCO-CEFTRIAZONE 1 g: Each vial contains 1 g sterile ceftriazone as ceftriazone sodium.

ADCO-CEFTRIAZONE 2 g: Each vial contains 2 g sterile ceftriazone as ceftriazone sodium.

There are no other ingredients.

What ADCO-CEFTRIAZONE looks like and contents of the pack

ADCO-CEFTRIAZONE 500 mg:

10 ml clear, colourless glass vial containing an almost white or yellowish sterile crystalline powder with an aluminium cap.

ADCO-CEFTRIAZONE 1 g:

10 ml clear, colourless glass vial containing an almost white or yellowish sterile crystalline powder with an aluminium cap.

ADCO-CEFTRIAZONE 2 g:

50 ml clear, colourless glass vial containing an almost white or yellowish sterile crystalline powder with an aluminium cap.

Reconstituted solutions may vary in colour from pale yellow to amber, depending on the concentration and length of storage.

Packs for i.m. or i.v. injection containing:

Single vials of dry substance equivalent to 500 mg ceftriazone packed in 1's, 4's, 5's or 10's in an outer carton.

Packs for i.m. or i.v. injection containing:

Single vials of dry substance equivalent to 1 g ceftriaxone packed in 1's, 4's, 5's or 10's in an outer carton.

Packs for i.v. infusion containing:

1 vial with dry substance equivalent to 2 g ceftriaxone packed in 1's, 4's, 5's or 10's in an outer carton.

Holder of Certificate of Registration

Adcock Ingram Critical Care (Pty) Ltd.

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ADCO-CEFTRIAXONE 2 g: 37/20.1.1/0044

NA: NS2 04/20.1.1/1958

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